K024047

510K SUMMARY

JAN 0 8 2003

Applicant:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person for ERBE USA:	Julie Stephens Consultant/President Regulatory Resources Group, Inc.
Contact Information:	550 Belgrave Lane Tucker, GA 30084 Tel: 770-923-7219 Fax: 770-216-1530
Date Prepared:	12/06/02
Common Name:	Argon Plasma Coagulator (APC) System
Trade/Proprietary Name:	ERBE VIO APC (Model APC 2) with Accessories

Note: VIO stands for Variable Cut and Coagulation.

Classification Name:	Electrosurgical cutting and coagulation device and accessories (21CFR878.4400)
Product Code:	79GEI
Legally Marketed Predicate Device:	ERBE Argon Plasma Coagulator (Model APC 300) and Accessories 510(k) Number: K963189

Device Description:

The ERBE Model APC 2 with Accessories is an argon plasma coagulation system and is used in conjunction with an ERBE VIO Electrosurgical Unit (ESU). The ESU provides high frequency (hf) voltage to electrically charge argon gas from the APC unit to form plasma in the gas stream when in close proximity to tissue. Current density upon arrival at the tissue surface from an APC instrument (applicator or probe) causes coagulation. The APC with the ESU has a color monitor display that provides the user with an on-screen tutorial as well as setting and operational information. The VIO APC/ESU system has various argon as well as argon assisted coagulation and cut modes. These modes have defined effect levels to provide the physician flexibility in interventional applications. Software in the ESU controls the microprocessor chip in the APC unit and APC Handles. The VIO ESU/APC system is programmable and has error monitoring features. There is an ERBE Communications Bus (ECB) Cable for the ESU to

communicate with the APC unit. A Pressure Reducer with Sensor is provided to regulate the argon gas going into the APC unit. Two types of APC Handles are available to activate the system. One of the Handles has a "ReMode" feature so that the physician can change between two pre-programmed modes via the Handle instead of having to touch the display screen. Specific technical information on the APC and Accessories can be found in Section IV. The APC unit and these accessories are supplied non-sterile and are reusable. Cleaning/Disinfection and as applicable sterilization instructions are provided in the respective User Manual or Notes on use. See Device Labeling in Section V, Attachment 2. An APC Membrane Filter is also apart of the system. A Filter is to be used for each case/interventional application. The Filter is connected between the APC unit (at the argon gas port) and an APC Handle or Connector Hose. The Filter creates a barrier to protect the APC unit from potential contamination. Filters are supplied sterile by means of ethylene oxide and are disposable (single use). They are contract manufactured and the sterilization cycle has been validated. See specific technical information in Section IV and general use information in the Notes on use in Section V, Attachment 1 for the Filter (Note: It is the same Filter used on the predicate device.).

Intended Use:

The ERBE VIO APC with Accessories is intended to deliver argon gas for argon plasma coagulation of tissue when used in conjunction with a compatible ERBE VIO Electrosurgical Generator (ESU) and applicators or probes.

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

The ERBE VIO APC (Model APC 2) with Accessories has the same intended use, principles of operation, and technological characteristics as the predicate APC in the previously cleared 510(k). Also, materials, size, protective circuits, performance characteristics, packaging, and labeling (except in the descriptions of the specific user instructions) are the same or similar.
Changes involve having an on-screen tutorial and interface display through the ESU for the APC. The modification also includes having the software of the ESU control the APC unit. In comparison to the predicate, other changes involve the ESU providing all the power to the APC through built in "HF Contacts" in the case of the units with footswitch activation being directly through the ESU. Furthermore, the gas flow rate range was made slightly lower with a one second shorter purge time. Modifications to the APC unit also include slight variations to existing modes and more effect levels over larger voltage ranges. All of the APC unit changes were done to have a user-friendlier platform with a less complicated system but provide the physician more flexibility in interventional applications. The specifics of the similarities and differences of the modes can be found in the Comparison Table. Technical information on the modes can be found in the APC 2 User Manual in Section V, Attachment 2. For the accessories a Sensor was added to the Reducer and a "ReMode" button was added to a Handle. The Sensor provides the VIO ESU/APC system with in-put gas pressure data. The

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"ReMode" button on the VIO APC Handle allows the physician to change between modes without having to touch the monitor of the equipment during a procedure. The performance standards/tests used/met were AAMI/ANSI HF 18, Electrosurgical Devices; EN 60601-1/IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety; EN 60601-1-2/IEC 60601-1-2, Medical Electrical Equipment Part 1: General Requirements for Safety; 2. Electromagnetic Compatibility Requirements and Tests; EN 60601-2-2/IEC 60601-2-2, Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment; and EN 60529, Degrees of Protection Provided by Enclosures (IP Code).
The software of VIO ESU controls the microprocessor chip in the APC 2 and APC Handles. It was upgraded to perform all the features/functions of the any compatible equipment. The Software is revision 1.1.2. General Principles of Software Validation; Final Guidance for Industry and FDA Staff, 01/11/02; Guidance for FDA Reviewers and Industry, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, 05/29/98; and EN 60601-1-4/IEC 60601-1-4, Medical Electrical Equipment Part 1: General Requirements for Safety, 4. Collateral Standard: Programmable Electrical Medical Systems were followed. Per the FDA Software Guidance Documents the software was determined to be a moderate level of concern.

Conclusion:

The 510(k) Guidance Document for General Surgical Electrosurgical Devices, 5/10/95 was followed for this submission. The Risk Analysis method used to assess the impact of the modification on the device performance and its components followed EN 1441: 1998, Medical Devices Risk Management. All of the changes were verified or validated. The changes did not raise safety or efficacy concerns nor adversely affect safety or effectiveness. That is the modified device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 8 2003

ERBE USA, Inc.
c/o Ms. Julie Stephens
Regulatory Resources Group, Inc.
550 Belgrave Lane
Tucker, Georgia 30084

Re: K024047
Trade/Device Name: ERBE VIO APC (Model APC 2) with Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 6, 2002
Received: December 9, 2002

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K024047

DEVICE NAME: Argon Plasma Coagulator (APC) System (VIO APC with Accessories)

INDICATIONS FOR USE:

The ERBE VIO APC with Accessories is intended to deliver argon gas for argon plasma coagulation of tissue when used in conjunction with a compatible ERBE VIO Electrosurgical Generator (ESU) and applicators or probes.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024047

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER P
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-
(Per 21 CFR 801.109) (Optional Forma